

### **AMENDMENT TO THE DRAWINGS**

Applicants submit a proposed amendment to Figure 7 (appended hereto) for approval by the Examiner in accordance with MPEP § 608.02(v). The proposed amendment is submitted to correct the error with respect to reference character “660” having two designations and to correct the error with respect to reference character “72” which should be “721”.

## **REMARKS**

Claims 1-42 were examined and rejected. Applicants cancel claims 22-23 and amend claims 1, 2, 6-8, 11-15, 25-27, and 31. Applicants submit additional claims 43-52 for consideration. Applicants submit that no new matter is added therein as amendments to the claims are to correct typographical errors, except: claim 1 which is supported at least at paragraph 82 and by claim 37; claim 12 which is supported at least by claim 1 and paragraph 44; claim 15 which is supported at least by claim 23 and paragraphs 56 and 59; claim 25 which is supported at least by claim 15; claim 27 which is supported at least by claim 1 and paragraphs 40 and 41; claim 31 which is supported at least by claim 24; new claims 43-44 which are supported at least at paragraph 40; new claim 45 which is supported at least at paragraph 82 and by claim 37; new claim 46 is supported at least by claim 2; new claims 47 is supported at least by claims 3 and 12; new claims 48-50 which are supported at least at paragraph 40; new claim 51 which is supported at least at paragraph 40; and new claim 52 which is supported at least at paragraph 49 of the application as originally filed, without limitation thereto. Applicants amend paragraphs 8, 13, 14, 40, 45-47, 50, 52, 55-57, 59-60, 66-67, 69, 81, 84, 88, 90-91, and 101 of the specification and the abstract. Applicants provide replacement Figure 7. Hence, Applicants respectfully request reconsideration of claims 1-21 and 24-42, as amended, and consideration of additional claims 43-52 in view of at least the following remarks.

### **I. Specification**

The Patent Office objects to the Abstract because “imageable marker properties” is not clear because there is not any structure. Applicants respectfully disagree for at least the reason that “imageable marker properties” are described at least at paragraphs 6, 40, 44, 52-55, 59 and 64-66 of the application, without limitation thereto. For example, an imageable marker property may be described by, without limitation thereto, a material property that is imageable by MRI, x-ray, fluoroscopy, CT scanners, or ultrasound. Some examples of such properties include, without limitation thereto, being radio-opaque, including gold, including platinum, being generated from materials chosen to minimize perturbation of a magnetic field, being a diamagnetic material, being generated from a paramagnetic material, including tungsten, including tantalum, made from a combination of materials having magnetic susceptibilities. In addition, an imageable marker property may describe, without limitation thereto, a structure capable of being imaged

using an imaging technique or an image modality; and/or may include a structure not capable of being imaged using a different imaging technique such as described at paragraphs 55-57 of the application. Moreover, an imageable marker property may include, without limitation thereto, using multiple imageable markers such as described at paragraphs 61 and 62; and/or using different sections of a sensor having multiple markers such as described at paragraphs 65 and 66 to make it possible to determine a device's orientation. Hence, Applicants assert that "imageable marker properties" describes at least the example structures noted above, without limitation thereto. Thus, Applicants respectfully request the Patent Office withdraw the objection above.

In addition, the Patent Office objects to the Abstract because the word "imagable" is misspelled. Applicants amend the specification, Abstract, and claims to correct this spelling to "imageable", and thus respectfully request the Patent Office withdraw the objection above.

The Patent Office objects to the disclosure paragraphs 52, 56, 61, 45, 50, 66, and 69 for various typographical errors. Applicants have amended the specification to cure these errors and respectfully request the Patent Office withdraw the objections above.

The Patent Office objects to the disclosure because the meaning of the phrases "imageable properties", "imaging properties", "multiple imaging properties" and "imageable marker properties" are not clear and need to include more information to clearly define what these phrases mean and their relationship to the sensor. Applicants assert that the terms "multiple imaging properties" describe more than one "imaging property". The terms "imageable properties", "imaging properties", and "multiple imaging properties" describe imageable marker properties, such as noted above. Hence, Applicants respectfully request the Patent Office withdraw the objection above with respect to the objection to the Abstract.

Finally, the Patent Office objects to the specification because "imagable" is misspelled. Applicants have corrected the spelling of this term and respectfully request the Patent Office withdraw the objection above.

## **II. Drawings**

The Patent Office objects to the drawings because reference character "660" has two designations. Applicants correct Figure 7 and respectfully request the Patent Office withdraw the objection above.

The Patent Office objects to the drawings because they fail to show 1330 and 1340 in Figure 12 as described in paragraph 99. Applicants respectfully disagree as 1330 and 1340 refer to Figure 13 as described in paragraph 99 and as shown in Figure 13. Hence, Applicants respectfully request the Patent Office withdraw the objection above.

### **III. Claim Objections**

The Patent Office objects to claim 22 being a substantial duplicate of claim 21. Applicants cancel claim 22 and thus respectfully request the Patent Office withdraw the objection above.

The Patent Office objects to claims 1, 2, 6-8, 11, 13, 14, 26 and 31 for various typographical errors. Applicants amend claims 1, 2, 6-8, 11, 13, 14, 26 and 31 to cure these errors and respectfully request the Patent Office withdraw the objection above for those claims.

### **IV. Claims Rejected Under 35 U.S.C. § 112**

The Patent Office rejects claims 1, 2, 6-8, 11, 13 and 14 under 35 U.S.C. § 112, second paragraph, because the structural cooperative relationships of “imageable marker properties” are omitted. Applicants respectfully disagree for at least the reasons cited above with respect to those terms and the objection to the Abstract. Specifically, examples of the structural cooperative relationships of “imageable marker properties” are described at various places in the specification as filed, without limitation thereto.

Moreover, the purpose of a claim is NOT to TEACH how the invention works, but rather, to set forth the BOUNDARIES of what the applicant considers to be the invention. The test for whether a claim meets the definiteness requirement is "whether one skilled in the art would understand the BOUNDS of the claim when read in light of the specification." *Personalized Media Communications v. Int'l. Trade Comm'n.*, 161 F.3d 696, 705, 48 U.S.P.Q.2D (BNA) 1880, 1888 (Fed. Cir. 1998)(emphasis added). As long as one of ordinary skill in the art would understand the SCOPE of the subject matter in the claims, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. *Id.*; MPEP 2173.04, citing *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971). Hence, Applicants respectfully request the Patent Office withdraw the rejection above.

The Patent Office rejects claim 25 under 35 U.S.C. § 112, second paragraph, because there are many different ways of relating two quantities and thus it is not clear what the relationship between position of the sensor device and marker is. Applicants respectfully disagree for at least the reason that examples of “relating the position of the sensor device relative to at least one of the plurality of markers” as claimed are given at paragraphs 4, 7, 43, 46, 50 and 55-58, without limitation thereto. In such examples, without limitation thereto, the position of the sensor may be relative to at least one of the markers based on a location, a relative coordinate system, an anatomical coordinate system and/or an internal coordinate system, without limitation thereto. Hence, for at least this reason, Applicants respectfully request the Patent Office withdraw the rejection above for claim 25.

The Patent Office rejects claim 25 under 35 U.S.C. § 112, second paragraph, because it is not clear how the position of the sensor device is determined based on relating. Applicants respectfully disagree for at least the reason that examples of “determining the position of the sensor device and the coordinate system based on the relating,” as claimed are described at least at paragraphs 51 and 56-58 of the application, without limitation thereto. In one such example, without limitation thereto, the location of the sensor device may be known relative to an array of markers imaged using a second modality, which does not image the sensor device, where the image of the array of markers is compared to an internal coordinate system calculated by imaging the markers and the sensor device using a first modality, without limitation thereto. Hence, for at least this reason, Applicants respectfully request the Patent Office withdraw the rejection above.

## **V. Claims Rejected Under 35 U.S.C. § 102**

The Patent Office rejects claim 1 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 6,402,689 to Scarantino et al. (“Scarantino”). It is axiomatic that to be anticipated every limitation of a claim must be disclosed in a single reference.

Applicants disagree with the rejection above of claim 1 for at least the reason that cited references do not disclose a sensor device having a plurality of imageable marker properties including a first imageable marker property to be imaged using a KV imager and a second imageable marker property to be imaged using a MV imager, as required by claim 1.

The Patent Office cites that a plurality of imageable marker properties is an inherent property of a sensor used in a medical application to be imaged. Scarantino describes sensor

units 50, 50' and 50'' for monitoring changes in physiological and kinetics of living systems for transmitting sensor data to a monitoring system (see Abstract, column 8 lines 53-64, and column 24 line 62 though column 25 line 17).

However, the Patent Office has not identified and Applicants are unable to find any disclosure or teaching in Scarantino that the sensors have a plurality of imageable marker properties including a first imageable marker property to be imaged using a KV imager and a second imageable marker property to be imaged using a MV imager, as required by claim 1. For example, the Patent Office has not identified and Applicants are unable to find any teaching or suggestion in Scarantino that the sensors are necessarily imageable using one imaging technique or modality; and imageable or not imageable using another different imaging technique or modality. For example, the sensors in Scarantino may not be imageable using any imaging technique or modality. Alternatively, the sensors in Scarantino may be intermittently or inconsistently imaged using any imaging technique or modality. Moreover, the Patent Office has not identified and Applicants are unable to find any motivation for the sensors in Scarantino to be imageable using a KV imager and a MV imager. Hence, for at least this reason, Applicants respectfully request the Patent Office withdraw the rejection above of claim 1.

The Patent Office rejects claims 12-14 and 27-30 under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,669,653 to Paltieli ("Paltieli").

Applicants respectfully disagree with the rejection above for claim 12 for at least the reason that the cited references do not disclose a sensor device having an imageable marker property and discerning an orientation of the sensor device in the body using an imaging technique, wherein the imageable marker property comprises a pattern from which orientation can be determined, as required by amended claim 12.

Paltieli describes using a position sensor to measure a predetermined point on a mother during labor (see Abstract). Specifically, Paltieli describes that each position sensor is capable of sensing a precise position and orientation in 3-dimensional space with respect to a reference (see column 5 lines 55-60). However, the Patent Office has not identified and Applicants are unable to find any teaching or disclosure in Paltieli of a sensor device having an imageable marker property and discerning an orientation of the sensor device in the body using an imaging technique, wherein the imageable marker property comprises a pattern from which orientation can be determined, as required by amended claim 12. Specifically, the Patent Office has not

identified and Applicants are unable to find any teaching or disclosure in Paltieli of an imageable marker property comprising a pattern from which orientation can be determined. Hence, for at least the reasons above, Applicants respectfully request the Patent Office withdraw the rejection above of claim 12.

Applicants also disagree with the rejection above of claim 27 for at least the reason that Paltieli does not disclose or teach means for providing telemetry regarding the monitored in vivo at least one physiological parameter; and means for identifying a position of the means for monitoring relative to an in vivo coordinate system with an imaging technique and a plurality of imageable marker properties, as required by amended claim 27. For example, Paltieli does not teach means for providing telemetry regarding the monitored in vivo at least one physiological parameter. Hence, for at least this reason, Applicants respectfully request the Patent Office withdraw the rejection above of claim 27.

The Patent Office rejects claims 31, 32, 35 and 36 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 5,810,007 to Holupka et al. ("Holupka").

Applicants respectfully disagree with the rejection above of claim 31 for at least the reason that the cited references do not disclose imaging a plurality of markers and an in vivo landmark using a first imaging modality, imaging the plurality of markers in a second modality, wherein the in vivo landmark is not imageable in the second modality. Specifically, Holupka teaches ultrasound probe 12 having transducer array 18 and fiducials 20 and 22 that are imaged in both the ultrasound image (Fig. 3) and in the simulator film image (Fig. 4) (see column 4 lines 2-17). Consequently, the Patent Office has not identified and Applicants are unable to find any disclosure or teaching of the above noted limitations of amended claim 31.

In addition, Applicants disagree with the rejection above for the reason that the cited reference does not disclose monitoring in vivo at least one parameter associated with a body, as required by amended claim 31. As noted, Holupka discloses an ultrasound probe. However, the Patent Office has not identified and Applicants are unable to find any teaching or suggestion of the above noted limitations of amended claim 31. Hence, Applicants respectfully request the Patent Office withdraw the rejection above of claim 31 for at least this additional reason.

## **VI. Claims Rejected Under 35 U.S.C. § 103**

Claims 2-11, 15-17, 18-21, 22-24 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Scarantino as applied to claim 1 above, and further in view of US Patent No. 6,785,571 to Glossop (“Glossop”). For a claim to be obvious, each limitation of that claim must be taught or suggested by at least one properly combined reference.

Applicants disagree with the rejection above for claim 15 for at least the reason the cited references do not teach or suggest identifying a position of the sensor device relative to an internal coordinate system using an imaging technique, wherein the internal coordinate system is based on a plurality of markers located in the body having an imageable marker property, and wherein identifying comprises identifying the position relative to at least one of the plurality of markers, as required by amended claim 15.

Glossop describes an insertable portion for holding a position sensor that can transmit a signal indicative of its position with respect to a field generator, where the position sensor includes fiducial markings (see Abstract). Specifically, the position sensor 20 moves in an electromagnetic field generated by field generator 14 and sensor coil 21 generates a position signal  $S_P$  that is indicative of the position of the position sensor (see column 4 lines 43-50), while fiducial marking 70 is imageable using a known imaging modality (see column 5 lines 54-60). However, generation of position signal  $S_P$  indicative of the position of position sensor 20 does not describe or suggest an internal coordinate system based on a plurality of markers located in the body having an imageable marker property, and wherein identifying comprises identifying the position relative to at least one of the plurality of markers, as required by amended claim 15.

Consequently, the Patent Office has not identified and Applicants are unable to find any teaching or suggestion in Glossop of the above noted limitations of claim 15. Hence, for at least this first reason, Applicants respectfully request the Patent Office withdraw the rejection above for claim 15.

Claims 33, 34 and 37-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Holupka.

Each dependent claim is patentable for the reasons discussed above for its base claim, in addition to the further non-obvious limitations added by each dependent claim. Hence, Applicants respectfully request the Patent Office withdraw the rejection for each dependent claim.



## **VII. Allowable Subject Matter**

Applicants note with appreciation the Patent Office's indication that claim 25 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, second paragraph, and to include all the limitations of the base and intervening claims.

Applicants have amended claim 25 to be in independent form.

## **VIII. Additional Claims 43-52**

Applicants submit that additional claim 44 is patentable over the cited references for at least the reason that the references do not teach, suggest, or make obvious adding an imageable property to a sensor device to make it imageable, as required by claim 44.

Applicants submit that additional claim 48 is patentable over the cited references for at least the reason that the references do not teach, suggest, or make obvious implanting in a body a first device configured to monitor in vivo a parameter associated with a patient; providing a drug enclosed in at least one of the first device and a second device; and releasing the drug in response to a signal received by the first device, as required by claim 48.

Also, each additional dependent claim is patentable for the same reason discussed above in support of its base claim, in addition to for the further non-obvious limitation added by each dependent claim. Hence, Applicants respectfully request the Patent Office allow additional claims 43-52.

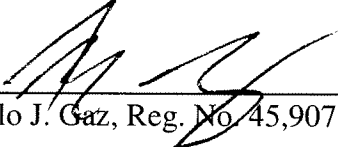
### CONCLUSION

In view of the foregoing, it is believed that all claims are now in condition for allowance and such action is earnestly solicited at the earliest possible date. If there are any additional fees due in connection with the filing of this response, please charge those fees to our Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

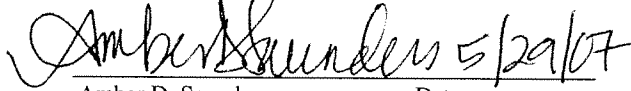
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